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| APPLICATION NUMBER | FILING DATE | FIRST NAMED APPLICANT | ATTORNEY DOCKET NO. |
|--------------------|-------------|-----------------------|---------------------|
| 08/536,750         | 09/29/95    | DRIZEN                | A 22890             |

NATH AND ASSOCIATES  
1835 K STREET NW  
SUITE 750  
WASHINGTON DC 20006

15M2/0303

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| EXAMINER |
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HULINA, A

|          |              |
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| ART UNIT | PAPER NUMBER |
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1501

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DATE MAILED:

03/03/97

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 11-12-96

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1,3-5,7-51 is/are pending in the application.

Of the above, claim(s) 15-51 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1,3-5,7-14 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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1. Applicant's election with traverse of Group 1 in Paper No. 6 is acknowledged. The traversal is on the ground(s) that the subject matter of the different groups of claims is not independent, but represents overlapping inventions that would require the same prior art search and examination. This is not found persuasive because the composition claims do not require that the composition be injected. Therefore, the method claims are searched on the basis of how they are used not what the composition contains and this entails a different search and examination. Claims 15-21 have been added to the original claims for examination.

The requirement is still deemed proper and is therefore made FINAL.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 3-5, 7-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sander et al.

Sander et al. Disclose a composition for effecting bone repair comprising a matrix selected from the group consisting of cellulose ether, collagen, a pharmaceutically acceptable salt of hyaluronic acid and mixtures thereof. The cellulose ethers include sodium carboxymethylcellulose (see col. 2, lines 57-64). The hyaluronic acid has a molecular weight not greater than about 1 million daltons (see col. 3, lines 20-22). The polymer matrix can contain an

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active drug (see col. 4, lines 51-66). Water is added to the polymer matrix to provide a moldable, semisolid composition which can then be implanted and shaped in a bone defect site (see col. 5, lines 39-42). Examples 9 and 10 show compositions containing a 1:1 ratio of sodium hyaluronate of molecular weight of about 600,000 daltons and hydroxypropylmethylcellulose.


4. Claims 1, 3-5, 7-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leshchiner et al.

Leshchiner et al. Disclose biocompatible viscoelastic two-phase gel slurries wherein the first phase comprises hyaluronic acid and its salts (col. 3, lines 59-62). The second phase comprises cellulose derivatives such as carboxymethylcellulose, hydroxypropylmethylcellulose, hydroxyethylcellulose (see col. 4, lines 45-50). The solvent can be water. The concentration of the hyaluronic acid can be from 0.15- 5 % by weight (see col. 6, lines 61-64). The composition may contain drugs (col. 7, lines 60-65). Example 12 shows a composition comprising a 1:1 CMC-hylan gel (see col 18, lines 31-37).

5. Applicant's arguments with respect to claims 1,3-5,7-14 have been considered but are moot in view of the new ground(s) of rejection.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy Hulina whose telephone number is (703) 308-2974.

AH  
March 1, 1997

  
Amy Hulina  
Primary Examiner  
Group 1500